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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/426,340 10/25/99 SANDAL

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EXAMINER

JOHANNSEN, D

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

07/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Advisory Action

Application No.  
09/426,340

Applicant(s)  
Sandal et al

Examiner  
Diana Johannsen

Art Unit  
1655



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jun 26, 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: See attachment.

4. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_
5. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: for the reasons set forth on the attachment to this Advisory Action and for the reasons of record in view of the non-entry of the After Final Amendment.
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
- Claim(s) allowed: none
- Claim(s) objected to: none
- Claim(s) rejected: 1-19, 21-25, and 27
9. ☐ The proposed drawing correction filed on \_\_\_\_\_ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
11. ☐ Other: \_\_\_\_\_

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**ATTACHMENT TO ADVISORY ACTION**

***New issues raised.***

1. Applicant's proposed amendments raise the following new issues under 35 U.S.C. 112, second paragraph that would require further consideration. Applicant has proposed amending independent claims 1 and 21 such that they require "preparing a gene library directly from the enriched pool of organisms" and "producing gene libraries directly from" an "enriched pool of organisms" (claim 21). The language "producing...directly" is vague and indefinite, because it is unclear as to how the inclusion of the term "directly" further limits the claims. For example, in what manner would "producing a gene library from" a pool of organisms differ from "producing a gene library directly" from that pool? It is clear from the teachings of the specification that a variety of steps are necessary to achieve gene library preparation (see, e.g., Example 3), and it is unclear as to what types of steps would be excluded by the language "directly" (i.e., when would the method become "indirect" as opposed to "direct"?). A clear and limiting definition of this language is not provided in either the specification or the art, such that one of skill would be apprised as to how the inclusion of the language "directly" would limit the methods of the claims. The response argues that this amendment clarifies that "the present invention avoids the need to perform time consuming and labor-intensive steps" and that "Duvick et al. plainly do not teach or suggest a method of preparing a gene library directly from an enriched pool of organisms". However, the specification teaches that gene library preparation may be achieved "by any suitable technique known in the art, non-limiting examples of which are described in Example 3 and 4".

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Similarly, Duvick et al disclose that "Microorganisms demonstrating fumonisin-resistance can be used to create a genomic library using standard techniques, well known in the art" (p. 24). Thus, while Applicants argue that their method is "direct" whereas Duvick et al's is supposedly "indirect", it appears that both the specification and Duvick et al disclose the use of methods well known in the art to prepare a library from an enriched pool. Accordingly, as it is unclear as to how the recitation "directly" would further limit the claims, entry of Applicants' proposed amendments would render the claims vague and indefinite.

***Claim Rejections - 35 U.S.C. § 112***

2. With respect to the rejection of claims 21-24 under 35 U.S.C. 112, second paragraph, as being indefinite over the recitation of the phrases "method of selecting a DNA sequence encoding a polypeptide of interest" and "selecting the DNA sequence of interest" in claim 21, the response argues that the claims are broad but not indefinite. The response argues that "the phrase 'selecting a DNA sequence' is defined in the specification as being 'performed by standard methods in the art'". However, the specification in fact does not define "selecting a DNA sequence" in this manner, but rather states that step d) (the "selecting" step) "may be performed by standard methods known in the art" (see specification p. 8). Accordingly, the specification does not in fact providing a limiting definition of this language such that it would be clear to a skilled artisan that "selecting a DNA sequence" refers to an actual, active method step as opposed to, e.g., a mental process of "selecting" that would not in fact further limit the physical method

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steps required by the methods claimed herein. Further, while it is acknowledged that the specification does exemplify in Example 5 steps of assaying for enzymatic activity that would be considered by one of skill in the art to constitute "selection", neither the specification nor the art provide a clear and limiting definition of the language "selecting a DNA sequence" that would apprise one of skill in the art that this language encompasses only such physical manipulations. Accordingly, applicants arguments are not persuasive.

*Conclusion*

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday from 7:00 a.m. to 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at 703/308-1152. The fax phone number for the Technology Center where this application or proceeding is assigned is 703/305-3014 or 305-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana Johannsen

July 18, 2001

  
CARLA J. MYERS  
PRIMARY EXAMINER